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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/580,679	06/06/2007	Marie-Danielle Nagel	0508-1162	5744

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EXAMINER	
ZISKA, SUZANNE E	
ART UNIT	PAPER NUMBER
1619	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DocketingDept@young-thompson.com

Office Action Summary	Application No.	Applicant(s)	
	10/580,679	NAGEL ET AL.	
	Examiner	Art Unit	
	SUZANNE ZISKA	1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 December 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19-22,24-26 and 28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19-22, 24-26 and 28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

Applicants' response of December 23, 2010, to the non-final action dated June 25, 2010, has been entered. Claims 19-22, 24 and 25 have been amended. Claim 23 was cancelled and claim 28 newly added. Accordingly, claims 19-22, 24-26 and 28 are pending in this application and are under current examination.

Status of Objections/Rejections

1. The objection to the claims in view of the misnumbering is withdrawn in view of the correct numbering as submitted in the amendment.

2. Claims 21 and 23-27 were rejected under 35 USC 112, second paragraph, for failing to distinctly point out and claim the invention.

The rejection of claims 21, 24 and 26 is withdrawn in view of the amendments to the claims. The rejection of claims 23 and 27 is withdrawn in view of the cancellation of the claims.

3. The rejection of claim 27 under 35 USC 101 is withdrawn in view of the cancellation of the claim.

4. The rejection of claims 19-22 under 35 U.S.C. 103(a) as being unpatentable over Legeay et al (USPN 2002/0193885) [Legeay] and Chabrecek et al (USPN 6,436,481) [Chabrecek] is maintained. The rejection is repeated below for reading convenience.

Legeay discloses implants which are modified on the surface by the creation of polar sites and which are coated with at least one layer of at least one hydrophilic polymer (paragraph [0021]) after creation of the polar sites (paragraph [0043]). Legeay discloses the creation of the polar sites on the surface of the base polymer material corresponds to increasing the proportion of carbonyl, hydroxyl or amine groups and free radicals (paragraph [0034]). Legeay discloses the hydrophilic polymer material can be

HPMC (paragraph [0046]) and PVA (paragraph [0049]). Legeay discloses the polar sites are created by plasma treatment, by corona effect discharge or by electromagnetic discharge at atmospheric pressure (paragraph [0063]). Legeay discloses that after the creation of the polar sites, a layer of at least one hydrophilic polymer is added to the implant by dipping for example ([0077]) followed by drying ([0078]). Legeay discloses that the base material can be modified on only one of its two surfaces, both surfaces, internal and external (Legeay claims 3 and 4).

Legeay differs from the claims in that the document fails to disclose a culture dish having PVA and CMC as layers on the base material. However, Chabrecek cures the deficiency.

Regarding claim 19, Legeay discloses coated implants having at least one hydrophilic polymer layer which can be HPMC and/or PVA. Chabrecek discloses coated articles wherein the primary coating comprises a plasma-induced polymer carrying reactive groups, which are reacted with monomeric compounds of semisynthetic or biological origins to provide hybrid type coated articles (secondary coatings) (Abstract). Chabrecek discloses that the primary polymeric coating can be PVA (column 12, lines 53-54). Chabrecek discloses the hybrid type coating promotes a selective growth of tissue on the outer surface and that a typical secondary coating can be a carbohydrate or a polysaccharide (column 11, lines 1-14).

Chabrecek discloses devices having primary and second coatings and which exhibit, inter alia, resistance to mechanical stress, and outstanding thermal, oxidative and hydrolytic stability, desirable permeation characteristics for liquids, gases, ions, nutrients and low molecular weight compounds (column 5, lines 40-51). Chabrecek also discloses the device is a coated article having a use as a bioanalytical system, affinity carrier or as permeselective membranes and implants. Chabrecek discloses (column 10, lines 6-20) that the coating can provide a substrate for cell attachment and tissue integration.

Both Legeay and Chabrecek disclose hydrophilic polymers suitable for both the internal and external layers. It would have been obvious to one of ordinary skill to modify a cell culture dish by adding the first and second layers as taught by both

Legeay and Chabrecek in view of the teachings of Chabrecek that the second coating will provide desired characteristics regarding adherence to the substrate such as reactivity, lubricity, durability, biocompatibility, bioaffinity, bioactivity, and wettability by solutions such as human body fluids (column 1, lines 5-18) in order to promote attachment of a particular cell type and obtain a system for bioanalysis as disclosed by Chabrecek (claim 19).

Regarding claim 20, Chabrecek discloses the substrate is any materially conventionally used for the manufacture of biomedical devices (column 10, lines 35-65, for example), thus rendering obvious a coating on a commercially available petri dish.

Regarding claim 21, Legeay discloses the layer has a thickness of between 10 and 100 nm (paragraph [0088]). It would have been obvious to one of ordinary skill to modify the layer thickness in order to obtain a predetermined thickness, dependent upon the goal at hand.

Regarding claim 22, the combination of Chabrecek and Legeay renders obvious the method of making the coated dish. Legeay discloses the polar sites are created by plasma treatment, by corona effect discharge or by electromagnetic discharge at atmospheric pressure (paragraph [0063]). Legeay discloses that after the creation of the polar sites, a layer of at least one hydrophilic polymer is added to the implant by dipping, for example ([0077]), followed by drying ([0078]). Chabrecek teaches devices prepared by a similar method having two layers.

All the claimed elements herein are known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

In light of the foregoing discussion, the claimed subject matter would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill would have had a reasonable expectation of success in producing the claimed invention. Therefore, in the absence of evidence to the contrary, the invention as a whole is *prima facie* obvious to one of skill in the art at the time the claimed invention was made, as evidenced by the references.

Applicants' arguments, filed 12/23/10, have been fully considered but not found persuasive.

A. Applicants argue

> One of skill would not consider modifying the polymer coating of LEGEAY to produce a bioactive layer as featured in the present claims. As disclosed in LEGEAY, the hydrophilic nature of their prosthesis "significantly reduces the formation of fibrous nodules over time, probably because of the lower adhesion of the fibroblasts to the envelope surface." (see, [0023]). One of skill would not consider modifying the polymer to produce a bioactive layer that includes a polysaccharide, such as CMC.

However, the desire to reduce formation of fibrous nodules over time is not incompatible with a bioactive layer. Legeay discloses that [0005] it has been known for a long time that the presence of prostheses inserted into living tissue causes the formation of retractile fibrous nodules which lead to a loss of flexibility of the breast after several months, and which can lead in some cases to rupture of the prosthesis membrane and that to resolve the problem [0006], several methods for hydrophilization of the external surface of a silicone polymer were reported. Thus contrary to Applicants' arguments, Legeay suggests hydrophilization of the surface to overcome the problem of rupture.

B. Applicants argue

> Second, LEGEAY teaches that the hydrophilic polymer can be at least one of a list of polymers including HPMC and/or PVA (see, [0045]-[0054]) LEGEAY further states that the hydrophilic polymer can include ""a mixture of several of the hydrophilic polymers above, in general a mixture of two or three of the hydrophilic polymers above" (see, paragraph [0055]). Thus, although LEGEAY leaves open the possibility of including more than one polymer, LEGEAY fails to recognize the possibility of including CMC among its list of polymers.

However, Applicants are arguing the reference alone and not in combination. Further, Legeay explicitly discloses the celluloses and their derivatives, especially carboxy methyl cellulose (CMC) [0046], can be used. Chabrecek discloses coated articles wherein the primary coating comprises a plasma-induced polymer carrying reactive groups, which are reacted with monomeric compounds of semi-synthetic or biological origins to provide hybrid type coated articles (secondary coatings) (Abstract). Chabrecek discloses that the primary polymeric coating can be PVA (column 12, lines 53-54). Chabrecek discloses the hybrid type coating promotes a selective growth of tissue on the outer surface and that a typical secondary coating can be a carbohydrate or a polysaccharide (column 11, lines 1-14). Chabrecek discloses (column 10, lines 6-20) that the coating can provide a substrate for cell attachment and tissue integration.

C. Applicants argue

> Lacking from the laundry list of second components in CHABRECEK, however, is any teaching or suggestion toward the use of CMC. Furthermore, CHABRECEK fails to teach or suggest anything regarding the use of CMC in combination with HPMC or PVA.

However, Legeay explicitly discloses use of CMC [0046] as discussed above.

D. Applicants argue

> One of ordinary skill in the art would not consider the covalent bonding reaction conditions of CHABRECEK in combination with the weak bonding (i.e., hydrogen bonds) coating methods of LEGEAY when modifying the coating to include a second CMC component.

However, claim 19-21are directed to a product and do not include any recitation of product bonds. Therefore, Applicants' arguments are not commensurate with the scope of the claims. Claim 22 requires the substrate be treated, the HPMC layer be deposited followed by subsequent deposition of the external layer. No claim claims any type of bond formation or bond strength. Further, because the prior art teaches the same or similar compounds for use as substrate coatings as do Applicants, if the prior

art compositions comprise covalent bonds in combination with weak bonds then Applicants' compositions would exhibit the same covalent/weak bond combinations once on the substrate. Applicants' arguments that one would not consider covalent bonding reactions in combination with weak bonding coating methods are without substantiation given the high similarity of coating compositions, not commensurate with the scope of any claim and as such are not persuasive.

E. Applicants argue

> Conversely, it would not have been obvious that polymers which form a "bioactive" layer when linked by hydrogen bonds could retain that bioactivity when covalently bonded. The covalent bonds give chemical and physical properties to the polymers that are different from hydrogen bonds.

However, Applicants' arguments are conjecture only and not found persuasive. The claims fail to require any limitations as to type of bonding. See response set forth above.

5. Applicants' claim amendments have necessitated the following new ground of rejection.

The rejection of claims 24-26 under 35 U.S.C. 103(a) as being unpatentable over Legeay et al (USPN 2002/0193885) [Legeay] and Chabrecek et al (USPN 6,436,481) [Chabrecek] as applied to claims 19-22 above and further in view of Adair et al (USPN 6,316,215) [Adair] is maintained and further applied to new claim 28 for reasons of record. The rejection is repeated below for reading convenience.

Legeay and Chabrecek differ from the claims in that the documents fail to disclose methods for screening of diseases. However, Adair cures the deficiency.

Adair discloses methods of cancer screening of cells grown in cell culture. It would have been obvious to one of ordinary skill to substitute the culture dishes of Legeay and Chabrecek for the culture plates of Adair in view of the teachings of

Chabrecek, disclosing that the coated article or dish can be used as a bioanalytical system and that the second coating will provide desired characteristics regarding adherence to the substrate such as reactivity, lubricity, durability, biocompatibility, bioaffinity, bioactivity, and wettability by solutions such as human body fluids (column 1, lines 5-18) in order to promote attachment of a particular cell type for further study.

Regarding claims 24-26 and 28, Chabrecek discloses the device is a coated article having used as a bioanalytical system, affinity carrier or permeselective membranes and implants. Thus, the use of the dishes in any of the listed methods is rendered obvious by the teachings of Chabrecek, disclosing coated devices have a wide range of uses.

Regarding claims 24 and 28, use of cell cultures for in vitro study of diseases or conditions is old and well known in the art as evidenced by Adair. Adair contacts cells with compounds and detects morphological changes and proliferative changes (relevant to new claim 28) (column 4, lines 35-44). Adair discloses that TCPP, for example, will not enter dead cells, thus demonstrating observation of and detection of cellular proliferation and synthesis. Failure to fluoresce indicates a healthy cell culture (column 4, lines 36-44). Further, Chabrecek discloses use of the plates as a bioanalytical system and discloses that a wide variety of biomaterials may be used on the surface (column 6, beginning line 6) and that any of the listed biomaterials are suitable for analytical and diagnostic techniques. Any of the listed biomaterials may be considered "antiaging" molecules, lacking evidence to the contrary. Further, Applicants' specification includes measurement of cellular proliferation as an indicator of "aging." Chabrecek discloses that carbohydrates, oligosaccharides, polysaccharides and peptides and proteins (column 6, beginning line 6) are all suitable for substrate molecules, thus rendering collagen an obvious choice for use in the bioanalytical system for the study of aging.

Regarding claims 25, 26 and 28, Adair discloses observing the cells by microscope in order to study the presence or absence of fluorescence, indicated by their morphology or differentiation. Quantification is disclosed; see figure 3 for example. Adair discloses a presumptive diagnosis of cancer may be made upon the presence or

absence of fluorescing cells (Abstract), thus disclosing the claimed method of "prognosing tumors" (claim 28).

From the teachings of the references, it is apparent that one of ordinary skill would have had a reasonable expectation of success in producing the claimed invention. Therefore, in the absence of evidence to the contrary, the invention as a whole is *prima facie* obvious to one of skill in the art at the time the claimed invention was made, as evidenced by the references.

Applicants argue

> Second, one of ordinary skill in the art would not merely substitute one type of dish for another. In particular, one would not substitute a cell culture dish for a bioactive dish having a bilayer coating comprising an internal primary layer made of HPMC or PVA and an external bioactive layer comprising CMC. The presently claimed dishes present an anti-adhesive coating that prevents the adhesion and the spreading of normal adhesive cell, inhibits their proliferation, improves their differentiation and induces apoptosis.

However, no claim recites an anti-adhesive coating. Applicants' coatings are the same as or similar to the coatings used in the cited prior art. Therefore the prior art coatings would be expected to have properties the same as, or similar to, the properties Applicants' coatings. Chabrecek discloses the coated article or dish can be used as a bioanalytical system and that the second coating will provide desired characteristics regarding adherence to the substrate such as reactivity, lubricity, durability, biocompatibility, bioaffinity, bioactivity, and wettability. One of ordinary skill would have been motivated to prepare a dish having a second coating in order to obtain desired characteristics such as reactivity, lubricity, durability, biocompatibility, bioaffinity, bioactivity, and wettability.

New Grounds of Objection

Claim 28 is objected to. Claim appears to be a literal translation into English from a foreign document and contains idiomatic errors. "Prognosing" is not a proper

verb. It is suggested that the claim be amended to a method of diagnosing a tumor cells sample.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUZANNE ZISKA whose telephone number is (571)272-8997. The examiner can normally be reached on Monday through Friday 9 AM to 5 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Blanchard can be reached on (571) 272-0827. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Fereydoun G Sajjadi/
Supervisory Patent Examiner, Art Unit 1617

/S. Z./
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